Remarks/Arguments

Claims 6-22, 24-43, and 45-50 are pending. Claims 6-12, 19-22, 24-40, and 46-50 were withdrawn by the Office in an Office Action dated April 18, 2005 as drawn to non-elected subject matter.

Claims 41 and 45 have been amended to recite a therapeutically effective amount of crystalline solid pantoprazole. This amendment is supported on page 10, line 25 to page 11, line 4 of the Application as filed.

Applicants appreciate that Examiner Patricia L. Morris conducted a telephonic interview with their representatives, Craig L. Puckett, Reg. No. 43,023, and Gina R. Gencarelli, Reg. No. 59,729, on February 22, 2007. Applicants, however, do not agree with Examiner Morris' description of the substance of the interview in the Interview Summary mailed on February 26, 2007. Examiner Morris drafted the Interview Summary after the completion of the interview and without any input from Applicants' representatives. In fact, Applicants' representatives did not have the opportunity to review the Interview Summary until after it was mailed. Rather than describing what was actually discussed during the interview, Examiner Morris simply regurgitated the arguments set forth in the Office Action as supporting the outstanding claim rejections. Applicants' response to these arguments is set forth in the remarks below.

Claims 13-18, 41-43, and 45 stand rejected under 35 U.S.C. § 102 (a), (b), and/or (e) as allegedly anticipated by U.S. publication No. 2003/0036554 to Avrutov et al. ("'554 publication"), U.S. patent No. 6,723,852 to Maimo ("'852 patent"), U.S. patent No. 4,758,579 to Kohl et al. ("'579 patent"), and Kohl, et al., *J. Med. Chem.*, 1992, 35, pp. 1049-1057 ("Kohl article"). Applicants respectfully traverse.

The Court of Customs and Patent Appeals and the Board of Patent Appeals and Interferences have consistently held it improper to apply a bright-line rule rendering new forms of known compounds *per se* anticipated by the prior art disclosure of the compounds, where the prior art does not enable one of skill in the art to make the new forms. *See, e.g., In re Cofer*, 354 F.2d 664, 667 (C.C.P.A. 1966) (concluding that "merely changing the form, purity or another characteristic of an old product" does not automatically render the claimed product unpatentable over the old product).

The Board, in several recent unpublished decisions, has repeatedly reversed 35 U.S.C. § 102 rejections of claims to new polymorphic forms of a compound as anticipated by the

known compound, applying the principles established by *Cofer*. Although these decisions are unpublished, Applicants cite them as illustrative of the Board's adherence to the governing law. For example, the Board in *Ex parte Andrews*, Appeal No. 2002-0941, 2003 WL 25277872 (Bd. Pat. App. & Interf. September 25, 2003) (attached hereto as "Attachment A"), reversed an examiner's rejection of a claim to a new polymorphic form of a compound having a particular x-ray diffraction pattern as anticipated by a prior art disclosure of the compound, where the prior art disclosure was silent as to the x-ray diffraction pattern recited in the claims. The Board reasoned that the examiner failed to make out a *prima facie* case of anticipation because he did not articulate a "reasonable basis for concluding that the prior art compound...meets all the limitations of the claims," for example, by pointing to a passage in the prior art reference disclosing the applicants' method for preparing the new crystalline polymorph. *Andrews*, 2003 WL at *2. *See also Ex parte Havens*, Appeal No. 2001-0091, 2003 WL 21279863, *2 (Bd. Pat. App. & Interf.) (attached hereto as "Attachment B") (reversing an examiner's rejection of claims to new S and T polymorphic forms of delavirdine mesylate over the prior art disclosure of delvaridine mesylate in an undefined state because the "examiner has provided no evidence or scientific reasoning to show that the [prior art compound] is in either the S or T crystal form"). Yet, as discussed in detail below, the Office demonstrates its willingness to disregard the above-described principles of law in in maintaining the anticipation rejection.

Each one of claims 13-18, 41-43, and 45 encompasses a "crystalline solid pantoprazole" having a particular powder x-ray diffraction ("PXRD") pattern and/or a particular infrared ("IR") pattern or a pharmaceutical composition thereof. As previously argued, none of the '554 publication, the '852 patent, the '579 patent, or the Kohl article discloses the recited PXRD and/or IR patterns. *See, e.g.*, Amendment dated September 5, 2006, p. 10. Thus, none of the cited references discloses each and every recitation of the claims, as is required for anticipation. *See, e.g., Motorola Inc. v. Interdigital Technology Corp.*, 43 USPQ2d 1481, 1490 (Fed. Cir. 1997).

Further, the Office has not articulated a reasoned basis for concluding that the cited references, although silent as to the recitations of the claims, nevertheless disclose the pantoprazole of the crystalline form recited in the claims. The Office simply makes the conclusory statements:

> [A] novel chemical product is identified first by its "chemical nature," i.e., elemental and atom content...*in the strictest*

> *sense, polymorphs are different crystalline forms of the* ***same pure substance*** *in which the molecules have different arrangements and/or different conformations of the molecules.*

and improperly shifts the burden to Applicants to come forward with evidence to establish that the cited references do not disclose pantoprazole of the crystalline form recited in the claims:

> Applicants have failed to present any single X[-]ray crystal diffraction of instant compound vis-à-vis the prior art compounds at the same parameters.

Office Action, p. 3 (emphases in original).

None of the cited references discloses any evidence that would reasonably indicate that the pantoprazole has the crystalline form recited in the claims. In particular, none of the cited references discloses Applicants' process for preparing pantoprazole of the crystalline form recited in the claims. *See Andrews, supra.*

Claims 13-18, 41-43, and 45 recite a crystalline form of pantoprazole that Applicants have denominated "Form II." Specification, p. 5, ll. 1-10. The specification describes that pantoprazole Form II is prepared by a "slurry method." *Id.* at p. 5, ll. 11-17. The slurry method comprises slurrying amorphous pantoprazole in a diluent selected from the group consisting of diethyl ether and methyl tert-butyl ether, and maintaining the slurry for a period of time sufficient to obtain pantoprazole Form II, which is preferably for about 24 to about 48 hours. The pantoprazole Form II thus obtained may then be recovered by decanting or filtering the slurry. *Id.*

The '554 publication discloses a process for preparing pantoprazole by oxidizing its corresponding sulfide, 5-(difluoromethoxy)-2-[[3,4-dimethoxy-2-pyridinyl)methyl]thio]-1H-benzamidazole, with either (i) a mixture of vanadyl (IV) acetylacetonate and tert-butyl hydroperoxide (TBHP) in ethanol or (ii) a mixture of Oxone® and sodium bicarbonate in methanol, followed by treatment with sodium metabisulfite. '554 publication, example 4, p. 4, ¶ 50; example 11, p. 5, ¶ 58. The pantoprazole is recovered from the reaction mixture by filtration, followed by washing. *Id.*

The '852 patent discloses the preparation of pantoprazole by oxidizing its corresponding sulfoxide with a mixture of ammonium molybdenate and sodium percarbonate in methanol, followed by treatment with acetic acid. The pantoprazole is recovered from the

reaction mixture by extraction with dichloromethane, followed by evaporation of the solvent. '852 patent, example 18, col. 9, ll. 38-53.

The '579 patent discloses processes for preparing benzamidazoles, such as pantoprazole, by oxidizing their corresponding sulfides with oxidizing agents such as m-chloroperoxybenzoic acid or sodium hypochlorite. *See* '579 patent, col. 14, l. 54 to col. 30, l. 37. The benzamidazoles are recovered by crystallization from organic solvents, such as a mixture of ethyl acetate and diisopropyl ether. *Id.*

The Kohl article discloses the crystallization of pantoprazole from a mixture of dichloromethane and diisopropyl ether. Kohl article, p. 1052, Table I, compound 1a.

None of the '554 publication, the '852 patent, the '579 patent, or the Kohl article discloses the preparation of crystalline pantoprazole from a slurry of amorphous pantoprazole in diethyl ether or methyl tert-butyl ether. In addition, the Office has not offered any reasoned basis for finding that one of ordinary skill in the art can produce pantoprazole Form II by the processes disclosed in the cited references.

In view of the foregoing arguments, the rejection of claims 13-18, 41-43, and 45 under 35 U.S.C. § 102(a), (b), and/or (e) as anticipated by the '554 publication, the '852 patent, the '579 patent, and the Kohl article cannot stand and should be withdrawn.

Claims 13-18, 41-43, and 45 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over the '554 publication, '852 patent, '579 patent, and the Kohl article, in view of U.S. patent No. 6,384,059 ("'059 patent"); U.S. publication No. 2004/0177804 ("'804 publication"), and general reference materials Haleblian, et al., *J. Pharm. Sci.*, 1969, 58, pp. 911-929 ("Haleblian"), Muzaffar, et al., *J. Pharmacy*, 1979, 1(1), pp. 59-66 ("Muzaffar"), Rouhi, *Chem. & Eng'g News*, Feb. 2003, pp. 32-35 ("Rouhi"), U.S. PHARMACOPEIA, 1995, pp. 1843-1844 ("USP 1995"), Jain, et al., *Indian Drugs*, 1986, 23(6), pp. 315-329 ("Jain"), Taday, et al., *J. Pharm. Sci.*, 2003, 92(4) ("Taday"), Brittain, et al., POLYMORPHISM IN PHARMACEUTICAL SOLIDS, 183-286 (Marcel Dekker 1999) ("Brittain"), and Concise Encyclopedia Chemistry, 1993, pp. 872-873 ("Encyclopedia"). Applicants respectfully traverse.

The U.S. Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. __, 127 S. Ct. 1727, 1740-41 (2007) recently addressed the proper mechanics of an obviousness rejection, stating that in determining motivation to arrive at a claimed invention with a reasonable expectation of the success:

> [I]t will often be necessary to look to interrelated teachings of multiple patents; to the effect of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, **this analysis should be made explicit**. (emphasis added).

The essence of the Office's rationale for rejecting the claims as obvious in view of the cited references is as follows:

> One having ordinary skill in the art would find the claims prima facie obvious because the instant claims differ from the known product merely by forms and the physical properties innate to the forms. It is well recognized in the pharmaceutical field that many solids exhibit polymorphism which is the innate nature of the particular drug.

Office Action, pp. 4-5.

Applicants do not dispute that the scientific literature confirms that many pharmaceutical solids exhibit polymorphism. *See, e.g.*, Brittain. However, in view of the U.S. Supreme Court's decision in *KSR*, as well as the decisions cited below, this fact alone is not legally sufficient to establish that the crystalline form of pantoprazole recited in the claims is *prima facie* obvious in view of the cited references.

In order to render a new form of a compound obvious, the prior art must do more than merely suggest its existence.

> [T]o have a reasonable expectation of success, one must be motivated to do more than merely to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.

Pfizer v. Apotex, 480 F.3d 1348, 1365 (Fed. Cir. 2007).

Applying the *Pfizer* reasoning, the Federal Circuit, its predecessor Court of Customs and Patent Appeals, and the Board of Patent Appeals and Interferences have consistently held that in order for a claim to new form of a known compound to be *prima facie* obvious, the prior art must both provide some guidance as to the new form of the compound and provide some guidance as to a process for preparing the new form of the compound, such as discussed in *In re Hoeksema*, 399 F.2d 269 (C.C.P.A. 1968).

The Court of Customs and Patent Appeals in *In re Hoeksema* reversed the Office's rejection of an N-psicofuranoside as obvious in view of the prior art disclosure of a

structurally similar homolog of the compound, concluding that "if the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in possession of the public" and, thus, "the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close relationships between their structures and those of the prior art compounds." *Id.* at 274. The Federal Circuit reiterated this position more recently in *In re Kumar*, 418 F.3d 1361 (Fed. Cir. 2005), reversing the Office's rejection of claims directed to aluminum oxide particles having a particular particle size distribution as obvious in view of a prior art disclosure of aluminum oxide particles. The reference was silent as to the particle size distribution. The Federal Circuit reversed the Office's obviousness rejection in part because the Office had not established that the prior art would have enabled one of skill in the art to produce aluminum oxide particles with the claimed particle size distribution. *See also* M.P.E.P. § 2144.09 (August 2006).

Over the past decade, the Board has repeatedly reversed § 103 rejections of claims to new polymorphic forms of known compounds, applying the principles established by the Court of Customs and Patent Appeals in *Hoeksema*. For example, in *Ex parte Gala*, Appeal No. 2001-0987, 2002 WL 851814, *3 (Bd. Pat. App. & Interf.) (attached hereto as "Attachment C"), the Board reversed an examiner's rejection of claims to loratadine polymorphic form 2 as *per se* obvious over the prior art disclosure of loratadine polymorphic form 1. Unconvinced by the examiner's reasoning, the Board held that the rejection was improper because "the examiner...has not adequately established that the prior art (1) suggests the polymorph form 2 of loratadine; or (2) discloses or renders obvious a method for making the polymorph form 2 of loratadine." The Board has also followed the reasoning set forth in *Gala* in several unpublished decisions.[1] Yet, the Office maintains this *per se* analysis, blatantly ignoring and dismissing well-established case law:

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[1] *See also Ex parte Havens, supra* (reversing a § 103 rejection of claims to delaviridine mesylate in the S and T crystal forms in view of the prior disclosure of delvaridine mesylate itself because the examiner had "provided no evidence or convincing reasoning why the prior art disclosure of delavirdine mesylate in an undefined state would have suggested the specific S and T crystal forms that are the subject of the instant claims"); *Ex parte Meisel*, Appeal No. 2002-0438, 2002 WL 32334598 (Bd. Pat. App. & Interf. October 10, 2002) (attached hereto as "Attachment D") (reversing a rejection of claims to polymorphs of a known compound as obvious in view of the prior art disclosure of the compound itself because the prior art did not teach or suggest that the compound had different crystalline structures); *Ex parte Polniaszek*, Appeal No. 2001-1805, 2003 WL 22282265 (Bd. Pat. App. & Interf.) (attached hereto as "Attachment E") (reversing a similar (continued...)

> Applicants merely provide unpublished Board decisions that reversed the examiner. The decisions are not persuasive because the allowance on one case has no bearing at all on another case.

Office Action, p. 5.

As explained in detail below, in maintaining the obviousness rejection, the Office attempts to couple the specific teaching of pantoprazole with the general teaching of polymorphism by piecing together the disclosures of 14 references, while using clipped or out-of-context quotations and intentionally misrepresenting references.

First, the primary references, the '554 publication, the '852 patent, the '579 patent, and the Kohl article, do not teach or suggest the recited crystalline form of pantoprazole. The Office asserts that the primary references "teach the crystal forms of the instant known compound as well as the pharmaceutical compositions." Office Action, p. 4. In particular, the Office points to example 4 of the '554 publication and claim 22 of the '579 patent. *Id.* As previously argued, Example 4 and claim 22 do not teach pantoprazole in the crystalline form recited in the claims. *See, e.g.*, Amendment dated September 5, 2006, p. 12. Further, none of the other primary references teaches pantoprazole in the crystalline form recited in the claims. *See id.*

Second, as discussed above, none of the primary references, either alone or in combination, teaches or suggests a suitable method for obtaining pantoprazole in the crystalline form recited in the claims. In order to obtain pantoprazole in the crystalline form recited in the claims, one of ordinary skill in the art would have to ignore the teachings of the '852 patent, the '579 patent, and the Kohl article, which disclose the recovery of pantoprazole from solution, rather than from a slurry. Further, one of ordinary skill in the art would have to disregard the solvents disclosed in the primary references and instead choose diethyl ether or methyl tert-butyl ether. None of the primary references provide any guidance to make such modifications.

Accordingly, the primary references do not provide any guidance as to the recited crystalline form of pantoprazole, or enable one of ordinary skill in the art to obtain the recited crystalline form, as required for a finding of obviousness.

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rejection of claims to polymorphic forms of a known compound and stating that "we wish to make it clear that 'reliance on per se rules of obviousness is legally incorrect'").

To remedy the deficiencies of the primary references, the Office cites the '059 patent and the '804 publication for the teaching that "the instant compounds and analogous omeprazole are known to exist in additional crystalline forms." Office Action, p. 4. The Office also cites Haleblian, Muzaffar, Jain, Brittain, and Taday for the general teaching that "compounds exist as polymorphs." *Id.* The Office also cites Rouhi, Muzaffar, USP 1995, and Encyclopedia for the general teaching that "at any particular temperature and pressure, only one crystalline form is thermodynamically stable." *Id.*

When one skilled in the art considers the primary references, which disclose the compound pantoprazole *per se*, in view of the '804 publication, which discloses polymorphs of pantoprazole sodium, the '059 patent, which discloses polymorphs of omeprazole, and the general references Haleblian, Muzaffar, Jain, Brittain, Taday, Rouhi, Muzaffar, USP 1995, and Encyclopedia, which discuss aspects of polymorphism, he is not motivated to make the crystalline form of pantoprazole recited in the claims. None of these numerous secondary references, either alone or in combination with the primary references, provides any guidance that pantoprazole exists in the crystalline form recited in the claims. Further, none of the secondary references, either alone or in combination with the primary references, provides any guidance as to the method of slurrying amorphous pantoprazole in diethyl ether or methyl tert-butyl ether to obtain pantoprazole in the crystalline form recited in the claims. Despite the 14 references cited, the Office cannot establish that the claims are *prima facie* obvious.

Thus, in rejecting the claims as obvious in view of these references, the Office at best has applied an "obvious to try" rationale, and at worst has applied a *per se* rule of obviousness of polymorphs. Both rationales are contrary to law. *See, e.g., In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

Moreover, the Office improperly shifts the burden to Applicants to present evidence of unexpected properties of the claimed crystalline form of pantoprazole without having made out a *prima facie* case of obviousness. The Office states:

> It is apparent that applicants need a reference to support that a **showing of unobvious properties is necessary.** Note Brittain et al., page 185 where it is stated: "*An additional incentive for isolating and identifying polymorphs that provides certain advantages is the availability of subsidiary patents for desirable polymorphic forms, or for retaining a competitive edge through unpublished knowledge.* **In 1990 Byrn and Pfeiffer found more than 350 patents on crystal forms granted on the basis of an advantage in terms of stability, formulation, solubility, bioavailability, ease of purification,**

etc." Applicants have failed to show any advantage for the instant polymorphs.

Office Action, p. 5 (emphases in original) (italicized portion added by Applicants to demonstrate the full context of the quote cited by the Office).

The Office misrepresents Brittain by quoting it out of context. When properly read in its full context, the Brittain quote does not support the Office's sweeping conclusion that a showing of unobvious properties is necessary to impart patentability on a new crystalline form of a compound. Instead, the quote merely serves as an illustration of reasons why obtaining new polymorphic forms is desirable. Brittain, pp. 184-185.

Further, the Office states "Applicants do not point to any objective evidence which demonstrates that the claimed compounds as a class exhibit any properties which are actually different form the closest prior compounds embraced by Mueller et al.," citing *In re Wilder*, 563 F.2d 457 (C.C.P.A. 1977) and *In re Hoch*, 428 F.2d 1341 (C.C.P.A. 1970). Office Action, p. 5. Applicants note that in *Wilder* and *Hoch*, the applicants were required to present objective evidence showing a difference in properties because *prima facie* obviousness was conceded. These cases are inapposite because Applicants have not conceded, and the Office has certainly not established, a case of *prima facie* obviousness. Further, Applicants request clarification of the Office's citation of "Mueller, et al" as disclosing the closest prior compounds. Applicants are unfamiliar with this reference because it has never been cited against the application by the Office. Applicants respectfully request that the Office provide them with a full citation for this reference so that they may respond to the Office's assertion.

Based on the foregoing arguments, the rejection of claims 13-18, 41-43, and 45 under 35 U.S.C. § 103(a) cannot stand and should be withdrawn.

Claims 13-18, 41-43, and 45 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking in written description. Applicants respectfully traverse.

Apparently giving little or no consideration to Applicants' previous arguments, the Office simply cuts and pastes its previous boilerplate written description rejection into the Office Action, alleging that the application lacks written description because "there is a lack of description as to whether the pharmaceutical carriers are able to maintain the compound in the polymorphic form claimed," "[t]he specification fails to describe the pharmaceutical compositions claimed in terms of their x-ray diffraction pattern or infrared spectrum data," and "the specification has...not described how the polymorph forms and compositions being claimed will be maintained and prevented from converting to other forms when used in the

treatment of diabetes mellitus and any and all unknown conditions associated therewith." Office Action, pp. 6-8 (emphasis added).[2] In response, Applicants rely on their previous arguments set forth on pages 15 to 18 of the Amendment dated September 5, 2006, hereby incorporated by reference.[3]

In addition, the Office now improperly requires Applicants to come forward with objective evidence to support the written description of the claims:

> Contra to applicants' arguments in the instant response, applicants have **failed to provide any objective evidence that the instant polymorphs are indeed maintained in the compositions.**

Office Action, p. 7 (emphasis in original).

This position is contrary to law. The written description analysis is based upon the specification; to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail such that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); M.P.E.P. § 2163(I) (August 2006). Extrinsic objective evidence is not required.

Further, the Office continues to confuse written description and enablement by again considering the factors set forth by *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988), which apply to enablement, as part of its written description rejection. Because the enablement requirement is separate and distinct from the written description requirement of 35 U.S.C. § 112, it is improper for the Office to treat written description and enablement as a single basis for rejection. *Vas-Cath, Inc.*, 935 F.2d at 1560. However, to the extent that the Office will make a proper enablement rejection in the next Office Action, Applicants hereby incorporate by reference their previous arguments set forth on pages 18 to 19 of the Amendment dated September 5, 2006.

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[2] Applicants note that pantoprazole is described in the specification as being used for the inhibition of gastric acid secretion, and not for the treatment of diabetes mellitus. *See* Specification, p. 6, l. 31 to p. 7, l. 1. The fact that the Office Action again recites the treatment of diabetes mellitus is further evidence of the "boilerplate" nature of the written description rejection.

[3] Applicants note that the Office again cites "Doelker" in support of its written description rejection. As stated on page 17 of the Amendment dated September 5, 2006, the Doelker reference is not listed in the "Notice of References Cited" attached to the March 3, 2006 Office Action or the current Office Action and is not identified by the Office other than by the shorthand "Doelker." Applicants again respectfully request that the Office identify this reference so that Applicants may have the opportunity to fully respond to the issues raised by the Office.

Claims 13-18, 41, and 45 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly failing to particularly point out and distinctly claim the invention. Applicants respectfully traverse.

As to claim 45, the Office asserts that the claim is indefinite because it "fails to recite an effective amount of active ingredient." Office Action, p. 11. This rejection has been rendered moot by the amendment of claim 45.

As to claims 13-18, 41, and 45, the Office asserts that the claims are indefinite because they "contain the generic name pantoprazole." Office Action, p. 12. The Office states that "[w]here a generic name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph," citing *Ex parte Simpson*, 218 U.S.P.Q. 1020 (Bd. Pat. App. & Interfer. 1982). *Id.* The Office, however, misconstrues the holding of *Simpson*. In *Simpson*, the Board upheld an examiner's rejection of a claim containing the trademark Hypalon® as indefinite. The Board based its holding in part on the proposition that:

> [T]o describe physical or other properties of a material by mere use of a trademark is also objectionable since it has the tendency to make the trademark descriptive of a product rather than leaving the trademark to serve its traditional purpose, i.e. to identify the source of origin of a product.

Simpson, 218 U.S.P.Q. at 1022, n.2.

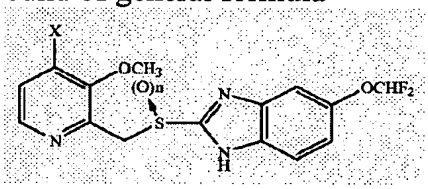
The Board in *Simpson* did not address the use of a generic chemical name in a claim at all, let alone announce a *per se* rule that use of a generic chemical name renders a claim indefinite, as the Office asserts. To the contrary, the Board's reasoning in *Simpson* actually supports the use of a generic chemical name to refer to a product in a claim because the generic chemical name describes the product, rather than identifies the source of the product.

The definiteness requirement of 35 U.S.C. § 112, second paragraph is satisfied so long as one of ordinary skill in the art would understand the metes and bounds of the claim when read in light of the specification. *See Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1378 (Fed. Cir. 2000). As previously argued, one of ordinary skill in the art would have readily recognized the term "pantoprazole" as a shorthand chemical name for the compound 5-(difluoromethoxy)-2-[[3,4-dimethoxy-2-pyridinyl)methyl] sulfinyl]-1H-benzimidazole at the time the application was filed. *See Merck Index*, 13th ed., p. 1256, compound 7084 (2001). Further, the term pantoprazole is explicitly defined in the specification as "5-(difluoromethoxy)-2-[[3,4-dimethoxy-2-pyridinyl)methyl] sulfinyl]-1H-

benzimidazole." Specification, p. 1, ll. 15-17. Because one of ordinary skill in the art would understand the metes and bounds of the claim term pantoprazole when it is read in light of the specification, the claims meet the requirements of 35 U.S.C. § 112, second paragraph. In fact, Examiner Morris has necessarily recognized the definiteness of the claim term "pantoprazole" by allowing, *inter alia*, U.S. patent Nos. 6,933,389 (issued on August 23, 2005) and 7,060,839 (issued on June 13, 2006), as follows:

> 1. A process for preparing crystalline Form-I of **Pantoprazole** sodium sesquihydrate, comprising: dissolving **Pantoprazole** free base in a solvent containing a stoichiometric amount of aqueous sodium hydroxide; b) adding an anti-solvent; c) cooling the mixture of (a) and (b) until a precipitate is formed; and d) isolating crystalline Form-I of **Pantoprazole** sodium sesquihydrate.

U.S. patent No. 6,933,389, col. 12, ll. 7-21 (emphases added).

> 1. A process for the preparation of **pantoprazole** comprising reacting a compound of general formula
>
> 
>
>
> where x is an atom of halogen and n=1, which when n=1 is reacted with a methoxylating agent, wherein the methoxylating agent is an alkali metal methoxide, wherein the methoxylation is conducted in an aprotic polar solvent, and wherein the reaction is carried out at a temperature between room temperature and 800°C.

U.S. patent No. 7,060,839, col. 13, l. 41 to col. 14, l. 20 (emphasis added).

For these reasons, the rejection of claims 13-18, 41, and 45 under 35 U.S.C. § 112, second paragraph cannot stand and should be withdrawn.

In view of the foregoing remarks, Applicants respectfully submit that the claims are in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same.

Respectfully Submitted,

KENYON & KENYON LLP

Date: May 29, 2007

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ATTACHMENT A

2003 WL 25277872 (Bd.Pat.App & Interf.)
(Cite as: 2003 WL 25277872 (Bd.Pat.App & Interf.))

***1** THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)
EX PARTE DAVID R. ANDREWS, WILLIAM LEONG, AND ANANTHA SUDHAKAR
Appeal No. 2002-0941
Application No. 09/166,445
September 25, 2003

Before WINTERS, SCHEINER, and GRIMES

Administrative Patent Judges

WINTERS

Administrative Patent Judge

ON BRIEF

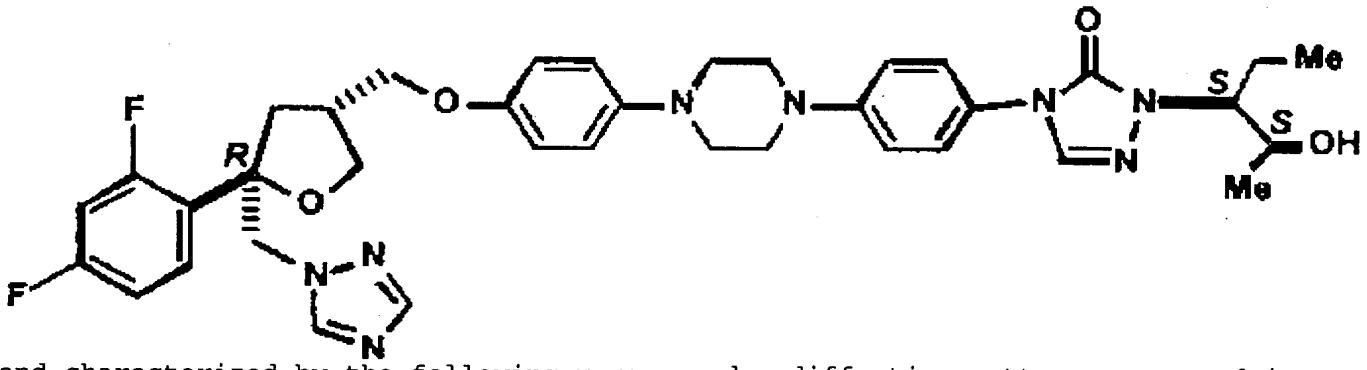
DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1 through 5, which are all the claims pending in the application.

The Invention

Applicants have discovered that the compound having formula I can exist in the form of three crystalline **polymorphs,** each distinctly different from each other and from the amorphous form in physico-chemical data, physical properties, and methods of preparation. These crystalline **polymorphs** are referred to as Form I, Form II, and Form III (specification, page 2, second paragraph). Form I, said to be the most stable of these forms, is the subject of representative claim 1 which reads as follows:

(1) A crystalline **polymorph** form of 1 of(-)-4-[4-[4-[4-[[(2R-cis)-5-(2,4-difluorophenyl)tetrahydro- 5-(1H-2,4-triazol-1-ylmethyl)furan-3-yl]-methoxy]phenyl]-1-piperazinyl] phenyl-2,4-dihydro-2-[(S)-1-ethyl-2(S)-hydroxylpropyl]-3H-1,2,4,-triazol-3-one represented by formula I



and characterized by the following x-ray powder diffaction pattern expressed in

terms of "d" spacing and relative intensities ("RI"):

d spacing (+-0.04)	R1
6.10	Medium
4.63	Medium
4.10	Wide
3.69	Wide
3.05	Wide

The Prior Art Reference

In rejecting applicants' claims under 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a), the examiner relies on the following reference:

Andrews et al. (Andrews) 5,625,064 Apr. 29, 1997

The Rejections

The appealed claims stand rejected as follows:

(1) claims 1, 2, and 3 under 35 U.S.C. § 112, second paragraph, as indefinite;

(2) claims 1 through 5 under 35 U.S.C. § 102(e) as anticipated by Andrews; and

(3) claims 1 through 5 under 35 U.S.C. § 103(a) as unpatentable over Andrews.

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials:

*2 (1) the instant specification, including all of the claims on appeal;

(2) applicants' Appeal Brief (Paper No. 17);

(3) the Examiner's Answer (Paper No. 18); and

(4) the above-cited prior art reference.

On consideration of the record, including the above-listed materials, we reverse each of the examiner's rejections.

Section 112

In our judgment, claims 1, 2, and 3 set out and circumscribe a particular area with a reasonable degree of precision and particularity; and the examiner's rejection of these claims under 35 U.S.C. § 112, second paragraph, for indefiniteness, lacks merit. We shall not belabor the record with extensive commentary on this point, but simply refer to applicants' discussion in the Appeal Brief, pages 3 and 4, with which we agree. Additionally, the examiner does not invite attention to any language or limitation in claims 1, 2, or 3 which would give rise to a case of indefiniteness.

The rejection under 35 U.S.C. § 112, second paragraph, is reversed.

Section 102(e)

The examiner argues that (1) Andrews describes a compound having formula I illustrated in claim 1 on appeal; and (2) Andrews discloses that that compound possesses antifungal activity. With respect to the particular polymorphic form recited in the appealed claims (crystalline **polymorph** form I), the examiner acknowledges that "Andrews is silent to [sic] as to nature of crystalline form produced" (Paper No. 18, page 4, first full paragraph). Nevertheless, the examiner would shift the burden of persuasion to applicants to establish that the prior art compound disclosed by Andrews lacks the x-ray powder diffraction pattern and infrared spectrum characteristics recited in applicants' claims ("evidence in verified form is needed that the prior art compound inherently lacks the characteristics relied on" id.). This constitutes reversible error.

As stated in the specification, page 2, second paragraph, applicants have discovered that the compound of formula I can exist in the form of three crystalline **polymorphs,** each distinctly different from each other and from the amorphous form. These crystalline **polymorphs** are referred to in the specification as Form I, Form II, and Form III and, according to applicants, Form I is the most stable.

The examiner does not deny that applicants' specification teaches any person skilled in the art how to make crystalline **polymorph** form I of the compound of formula I illustrated in claim 1 on appeal. Nor can the examiner point to any passage in Andrews disclosing applicants' method for making crystalline **polymorph** form I, or establishing a reasonable basis for concluding that the prior art compound disclosed by Andrews meets all the limitations of the claims. On the contrary, the examiner acknowledges that "Andrews is silent to [sic] as to nature of crystalline form produced" (Paper No. 18, page 4, first full paragraph).

*3 On these facts, the examiner is not in a position to invoke the principles enunciated in In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596-97 (CCPA 1980); In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977); and In re Swinehart, 439 F.2d 210, 213, 169 USPQ 226, 229 (CCPA 1971). Rather, the facts here more closely resemble those presented to another merits panel of this board in Ex parte Skinner, 2 USPQ2d 1788 (Bd. Pat. App. & Int. 1986). As stated by the board in Skinner:

> We are mindful that there is a line of cases represented by In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971) which indicates that where an examiner has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, the examiner possesses the authority to require an applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. Nevertheless, before an applicant can be put to this burdensome task, the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art. In the case before us, no such evidence or reasoning has been set forward. [id. at 1789]

The rejection under 35 U.S.C. § 102(e) is reversed.

Section 103(a)

Citing Ex parte Hartop, 139 USPQ 525 (Bd. App. 1962), the examiner apparently would invoke a per se rule of obviousness, viz., that merely changing the form, purity, or another characteristic of an old product, the utility remaining the same as that for the old product, does not render the claimed product patentable. The examiner argues that (1) crystalline **polymorph** form I of the compound of formula I

illustrated in claim 1 on appeal is merely a different polymorphic form of the compound disclosed by Andrews having formula I; (2) crystalline **polymorph** form I recited in applicants' claims and the compound disclosed by Andrews having formula I both possess antifungal activity; and (3) accordingly, the subject matter sought to be patented in claims 1 through 5 would have been prima facie obvious in view of Andrews. We disagree.

First, as stated in In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995):

> The use of per se rules, while undoubtedly less laborious than a searching comparison of the claimed invention--including all its limitations--with the teachings of the prior art, flouts section 103 and the fundamental case law applying it. Per se rules that eliminate the need for fact-specific analysis of claims and prior art may be administratively convenient for PTO examiners and the Board. Indeed, they have been sanctioned by the Board as well. But reliance on per se rules of obviousness is legally incorrect and must cease.

***4** Second, the principle of law enunciated in Ex parte Hartop, 139 USPQ 525 (Bd. App. 1962) has been substantially discredited in In re Cofer, 354 F.2d 664, 667-<c><c>68, 148 USPQ 268, 270-71 (CCPA 1966).

Third, on this record, the examiner has not adequately explained how a person having ordinary skill would have been led from "here to there," i.e., from the Andrews compound having formula I to the crystalline **polymorph** form I recited in claims 1 through 5.

The rejection under 35 U.S.C. § 103(a) is reversed.

Conclusion

In conclusion, for the reasons set forth, we do not sustain the rejection of claims 1, 2, and 3 under 35 U.S.C. § 112, second paragraph; the rejection of claims 1 through 5 under 35 U.S.C. § 102(e); or the rejection of claims 1 through 5 under 35 U.S.C. § 103(a).

The examiner's decision rejecting claims 1 through 5 is reversed.

REVERSED

BOARD OF PATENT APPEALS AND INTERFERENCES

Sherman D. Winters

Administrative Patent Judge

Toni R. Scheiner

Administrative Patent Judge

Eric Grimes

Administrative Patent Judge

Schering-Plough Corporation

Patent Department (K-6-1, 1990)

2000 Galloping Hill Road

Kenilworth, NJ 07033-0530

2003 WL 25277872 (Bd.Pat.App & Interf.)

END OF DOCUMENT

ATTACHMENT B

2003 WL 21279863 (Bd.Pat.App & Interf.)
(Cite as: 2003 WL 21279863 (Bd.Pat.App & Interf.))

*1 THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)
EX PARTE JEFFREY L. HAVENS, DONALD P. SMITH, MICHAEL S. BERGREN AND MARK A. LYSTER
Appeal No. 2001-0091
Application No. 08/732,254

NO DATE REFERENCE AVAILABLE FOR THIS DOCUMENT

BRUCE STEIN

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INTELLECTUAL PROPERTY LEGAL SERVICES

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KALAMAZOO, MI 49001

Before WINTERS, ROBINSON, and GRIMES

Administrative Patent Judges

GRIMES

Administrative Patent Judge

ON BRIEF

DECISION ON APPEAL

An oral hearing in this case was scheduled for November 27, 2001. Upon reviewing the case, however, we have determined that an oral hearing will not be necessary and we render the following decision based on the record.

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 and 2. Claims 1 and 2 are directed to specific crystal forms (form "S" and form "T," respectively) of 1-[5- Methanesulfonamidoindolyl-2-carbonyl]-4-[3-(1-methylethylamino)-2-pyridinyl]-piperazine. monomethanesulfonate salt. [FN1] The claims list the powder **X-ray diffraction** measurements that distinguish the claimed crystal forms from other forms of delavirdine mesylate.

The examiner relies on the following reference:

Palmer et al. (Palmer) 5,563,142 Oct. 8, 1996

Claims 1 and 2 stand rejected under 35 U.S.C. § 102(e) as anticipated by Palmer.

Claims 1 and 2 also stand rejected under 35 U.S.C. § 103 as obvious over Palmer.

Claims 1 and 2 also stand rejected for both statutory and obviousness-type double patenting, based on the claims of Palmer.

We reverse all of the rejections.

Discussion

The claims are directed to delavirdine mesylate in the S crystal form (claim 1) or in the T crystal form (claim 2). The examiner rejected the claims, under several different rationales, over the Palmer patent.

1. Statutory double patenting

The examiner rejected the claims under 35 U.S.C. § 101 "as claiming the same invention as that of claim 11 of prior U.S. Patent No. 5563142." Examiner's Answer, page 4. The examiner explained that "[i]n the absence of evidence showing otherwise, either of the instant claims may be the same compound recited in US'142." Id.

"35 U.S.C. § 101 prevents two patents from issuing on the same invention.... A good test, and probably the only objective test, for 'same invention,' is whether one of the claims could be literally infringed without literally infringing the other. If it could be, the claims do not define identically the same invention.... If it is determined that the same invention is being claimed twice, 35 U.S.C. § 101 forbids the grant of the second patent." In re Vogel, 422 F.2d 438, 441, 164 USPQ 619, 621-22 (CCPA 1970).

***2** Here, the patent's claim 11 is directed to delavirdine mesylate, without limitation as to crystal form. Instant claims 1 and 2 are directed to delavirdine mesylate in the S and T crystal forms, respectively. Thus, delavirdine mesylate in any crystal form other than S or T, or in a noncrystalline form, would infringe Palmer's claim 11 without infringing either of the claims on appeal. Therefore, the claims on appeal are not directed to the "same invention" as Palmer's claim 11 and are not unpatentable on that basis. The rejection under 35 U.S.C. § 101 is reversed.

2. Anticipation

The examiner rejected the claims under 35 U.S.C. § 102(e) on the basis that "Palmer discloses by name the same chemical compound as the mono methanesulfonate salt. See claim 11 in the US patent. In view of this fact evidence is needed that the prior art compound inherently lacks the characteristics (**x-ray diffraction** spectra recited in claims 1 and 2) relied on herein." Examiner's Answer, page 3.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "An inherent structure, composition or function is not necessarily known.... Insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation." Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

"'Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."' In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (quoting Hansgirg v. Kemmer, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939)). When the inherent properties of a prior art product are at issue, "the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art" before the burden is shifted to the applicant to disprove the inherency. Ex parte Skinner, 2 USPQ2d 1788, 1789 (Bd. Pat. App. Int. 1986).

Here, the claims on appeal are not directed to delavirdine mesylate per se, but are limited to the S and T crystal forms of that compound. Therefore, to anticipate the claims, the prior art must disclose delavirdine mesylate in the S and T crystal forms. The examiner has provided no evidence or scientific reasoning to show that the delavirdine mesylate disclosed and claimed by Palmer is in either the S or T crystal form. Therefore, the examiner has not made out a prima facie case of anticipation by inherency.

***3** The examiner's attempt to shift the burden of proof to Appellants was premature. The burden shifts to the applicant only if the examiner can show, by evidence or scientific reasoning, a reasonable basis for concluding that the prior art product meets all the limitations of the claims. The examiner has provided no basis for such a conclusion in this case. The rejection under 35 U.S.C. § 102 is reversed.

3. Obviousness

The examiner rejected the claims under 35 U.S.C. § 103 on the basis that Palmer "discloses the free form of the instant sulfonate salts for use in treating HIV." Examiner's Answer, page 3. The examiner concluded that the corresponding methanesulfonate salt would have been an obvious variant because Palmer "teaches and in fact prefers the use of salt forms for better solubility and crystallinity," and methanesulfonate salts were exemplified for compounds other than delavirdine mesylate. Id., pages 3-4.

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993).

The examiner's obviousness rejection seems to suffer the same infirmity as her anticipation rejection, namely, that it is directed to delavirdine mesylate per se, rather than to the specific S and T crystal forms of delavirdine mesylate that are the subject of the claims on appeal. The examiner has provided no evidence or convincing reasoning why the prior art disclosure of delavirdine mesylate in an undefined state would have suggested the specific S and T crystal forms that are the subject of the instant claims.

Nor has the examiner established that Palmer would have enabled those skilled in the art to make the claimed S and T crystal forms of delavirdine mesylate. Appellants' specification discloses specific conditions for recrystallizing delavirdine mesylate that produce the S and T crystal forms. See pages 2-4 and Examples 1-8. Palmer does not disclose or suggest even the existence of the S and T crystal forms of delavirdine mesylate, let alone how to make them. As stated in In re Hoeksema:

> [I]f the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close relationships between their structures and those of prior art compounds. ***4** 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968) (footnote omitted).

Since the examiner has not established that Palmer would have rendered the claimed invention obvious to those skilled in the art, she has not made out a prima facie case under 35 U.S.C. § 103. The rejection for obviousness is reversed.

4. Obviousness-type double patenting

The examiner rejected the claims for obviousness-type double patenting over Palmer's claim 11. The examiner argues that the instant claims and Palmer's claim 11 are not patentably distinct because they contain "overlapping subject matter" and because Palmer also claims the free form of delavirdine, which is an obvious variant of delavirdine mesylate. Examiner's Answer, page 4.

> Obviousness-type double patenting ... requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent. Its purpose is to prevent an unjustified extension of the term of the right to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner later.

In re Berg, 140 F.3d 1428, 1431, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998) (citation omitted, emphasis added).

All proper double patenting rejections, of either type, rest on the fact that a patent has been issued and later issuance of a second patent will continue protection, beyond the date of expiration of the first patent, of the very same invention claimed therein (same invention type double patenting) or of a mere variation of that invention which would have been obvious to those of ordinary skill in the relevant art (obviousness-type double patenting). In the latter case, there must be some clear evidence to establish why the variation would have been obvious. In re Kaplan, 789 F.2d 1574, 1579-80, 229 USPQ 678, 683 (Fed. Cir. 1986) (emphasis in original).

Thus, a proper rejection for obviousness-type double patenting requires showing that the later-claimed subject matter "would have been obvious to those of ordinary skill in the relevant art" based on the claims in the earlier patent. As discussed above, the examiner has pointed to nothing in either the claims or the disclosure of the Palmer patent that would have suggested the S and T crystal forms of delavirdine mesylate to a person of ordinary skill in the art. We therefore reverse the rejection for obviousness-type double patenting.

Summary

We reverse all of the rejections because the examiner has not established that the prior art disclosed or suggested the claimed S and T crystal forms of delavirdine mesylate.

REVERSED

BOARD OF PATENT APPEALS AND INTERFERENCES

***5** SHERMAN D. WINTERS

Administrative Patent Judge

DOUGLAS W. ROBINSON

Administrative Patent Judge

ERIC GRIMES

Administrative Patent Judge

FN1. This compound is also known as delavirdine mesylate, Appeal Brief, page 2, and we will refer to it as such.

ATTACHMENT C

2002 WL 851814 (Bd.Pat.App & Interf.)
(Cite as: 2002 WL 851814 (Bd.Pat.App & Interf.))

Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)
*1 EX PARTE DINESH GALA AND DONALD J. DIBENEDETTO
Appeal No. 2001-0987
Application 09/169,109

NO DATE REFERENCE AVAILABLE FOR THIS DOCUMENT

Thomas D. Hoffman

Schering-Plough Corporation

Patent Department K-6-1 1990

2000 Galloping Hill Road

Kenilworth NJ 07033-0530

Before WINTERS, WILLIAM F. SMITH, and ROBINSON

Administrative Patent Judges

Winters

Administrative Patent Judge

ON BRIEF

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1 through 8, which are all of the claims pending in this application.

THE INVENTION

Applicants' invention relates to a crystalline "polymorph form 2 loratadine" having a specified x-ray powder diffraction pattern; a pharmaceutical composition comprising an anti-allergic effective amount of the polymorph form 2 loratadine and a pharmaceutically acceptable carrier; and a method of treating allergic reactions in a mammal by administering to the mammal an anti-allergic effective amount of polymorph form 2 loratadine. Claim 1, which is illustrative of the subject matter on appeal, reads as follows:

1. Polymorph form 2 loratadine having the following x-ray powder diffraction pattern expressed in terms of "d" spacing and relative intensities("RI").

d spacing (+-0.05)	RI
8.95	Weak
6.37	Weak
5.64	Weak

THE REFERENCES

The prior art references relied on by the examiner are:

Villani 4,282,233 Aug. 4, 1981

Sims et al. (Sims) WO 95/01792 Jan.19, 1995
(PCT Application)

THE REJECTIONS

Claims 1 through 8 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combined disclosures of Villani and Sims. Claims 1 through 8 further stand rejected under the judicially created doctrine of obviousness-type double patenting over claim 7 of Villani in view of Sims.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including Figures 1 and 2, and all of the claims on appeal; (2) the Appeal Brief (Paper No. 10); (3) the Examiner's Answer (Paper No. 11); and (4) the above - cited prior art references.

On consideration of the record, including the above - listed materials, we reverse the examiner's rejections.

DISCUSSION

The question here is whether the combined disclosures of Villani and Sims support a conclusion of obviousness of claims 1 through 8, which recite the crystalline polymorph form 2 of loratadine having a unique x-ray powder diffraction pattern and infrared spectrum. We answer that question in the negative.

***2** Villani discloses polymorph form 1 of loratadine, but does not disclose or suggest that loratadine may assume distinct, crystalline polymorphic forms having different physical properties. Nor does Villani teach a person having ordinary skill in the art how to make polymorph form 2 of loratadine.

The Sims reference does not cure the deficiencies of Villani. Sims discloses a list of 16 non-sedating antihistamines, including loratadine, useful in combination therapy (Sims, page 8, lines 3 through 6). After listing those antihistamines, Sims refers to "a pharmaceutically acceptable salt, hydrate, or polymorph thereof" (id., lines 6 and 7). That reference to pharmaceutically acceptable salts, hydrates, or polymorphs, however, does not teach a person having ordinary skill in the art that loratadine may assume distinct, crystalline polymorphic forms having different physical properties. Rather, it appears that the above-quoted language constitutes boilerplate; and that Sims refers generally to pharmaceutically acceptable salts, hydrates, or polymorphs of any one of 16 non-sedating antihistamines without specifically suggesting that loratadine is capable of existing in the form of distinct crystalline polymorphs. On this point, we disagree with the examiner's finding that "Sims expressly teaches that loratadine may be in the form of polymorphs" (Examiner's Answer, page 3, lines 10 and 11). Nor does Sims teach a person having ordinary skill in the art how to make polymorph form 2 of loratadine.

On this record, applicants, and applicants alone, disclose that "loratadine can exist in the form of two distinct crystalline polymorphs, each having distinctly different physical properties" (Specification, page 2, first full paragraph). Applicants have discovered specific solvents and experimental conditions, producing a distinctly different polymorph form 2 of loratadine (Specification, page 3, last paragraph). Applicants discovered that crystallization of loratadine (prepared as described in U.S. Patent No. 4,282,233) from toluene, t-butylmethylether, heptane, or mixtures thereof, produce a polymorph form 2 loratadine. Applicants also discovered that using a t-butylmethylether-toluene mixture is preferred (Specification, page 4, second paragraph). This information stems from applicants' specification, but not from the cited prior art. Further, neither Villani nor Sims

discloses or renders obvious a method for making polymorph form 2 loratadine. As stated in In re Hoeksema, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968),

> [I]f the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close relationships between their structures and those of prior art compounds. [footnote omitted]

***3** The examiner relies heavily on this proposition of law set forth in Ex parte Hartop, 139 USPQ 525, 527 (Bd. Pat. App. 1962):

> [M]erely changing the form, purity or another characteristic of an old product, the utility remaining the same as that for the old product, does not render the claimed product patentable.

According to the examiner, polymorph form 2 loratadine is merely another form of an old product (polymorph form 1 loratadine) and both forms possess the same utility. Accordingly, the examiner concludes that applicants' claims, reciting polymorph form 2 loratadine, are unpatentable. We disagree. Here, we invite attention to In re Cofer, 354 F.2d 664, 667, 148 USPQ 268, 271 (CCPA 1966), where the court substantially discredited PTO reliance on the above-quoted proposition of law in Hartop. Like the situation presented in Cofer, the examiner in this case has not adequately established that the prior art (1) suggests the polymorph form 2 of loratadine; or (2) discloses or renders obvious a method for making the polymorph form 2 of loratadine.

Accordingly, the examiner's rejection of claims 1 through 8 under 35 U.S.C. § 103(a) as unpatentable over Villani in view of Sims is reversed. For essentially the same reasons, the rejection of claims 1 through 8 under the judicially created doctrine of obviousness-type double patenting over claim 7 of Villani in view of Sims is also reversed.

The examiner's decision rejecting claims 1 through 8 is reversed.

REVERSED

BOARD OF PATENT APPEALS AND INTERFERENCES

Sherman D. Winters

Administrative Patent Judge

William F. Smith

Administrative Patent Judge

Douglas W. Robinson

Administrative Patent Judge

2002 WL 851814 (Bd.Pat.App & Interf.)

END OF DOCUMENT

ATTACHMENT D

2002 WL 32334598 (Bd.Pat.App & Interf.)
(Cite as: 2002 WL 32334598 (Bd.Pat.App & Interf.))

*1 THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)
EX PARTE PETER MEISEL, KARL-FRIEDRICH LANDGRAF, JURGEN SCHAFER, WILFRIED THIEL, MATTHIAS RISCHER, ALFRED OLBRICH, AND BERNHARD KUTSCHER
Appeal No. 2002-0438
Application No. 09/181,671
Heard: October 10, 2002

VENABLE, BAETJER, HOWARD & CIVILETTI, LLP

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WASHINGTON, DC 20005-3917

Before WINTERS, SCHEINER, and GREEN

Administrative Patent Judges

GREEN

Administrative Patent Judge

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-3 and 16. Claim 1 is drawn to Modification A of the compound 2-amino-4-(4-fluorobenzylamino)-1-ethoxy-carbonylaminobenzene, wherein the modification is "characterized by the X-ray diffractogram, reflections not coinciding with the reflections of the other two modifications being observed, inter alia, at 6.97° 2<<THETA>> (12.67 Å), 18.02° 2<<THETA>> (4.92 Å) and 19.94° 2<<THETA>> (4.45 Å)." Claims 2 and 3 are drawn to Modification B and Modification C of the 2-amino-4-(4-fluorobenzylamino)-1-ethoxy-carbonylaminobenzene compound, each modification being defined by peaks appearing on the X-ray diffractogram. Claim 16 is drawn to pharmaceuticals "comprising the modification A, B or C" of the compound, "and, if appropriate, exipients and or auxiliaries." [FN1]

The examiner relies upon the following art:

German Patent Application
Dieter et al. (Dieter) DE 42 00 259 Jul. 15, 1993

Kirk-Othmer, "Crystallization," Encyclopedia of Chemical Technology, 4th Ed., Vol. 7, pp.700-702 (1993)

The claims stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Dieter and Kirk-Othmer. After careful consideration of the record and the issue before us, we reverse.

DISCUSSION

The Examiner's Answer rejects claims 1-3 and 16 as being obvious over the combination of Dieter and Kirk-Othmer. Dieter is cited for teaching the compound 2-amino-4-(4-fluorobenzylamino)-1-ethoxy-carbonylaminobenzene, as well as its use in

pharmaceutical compositions. Dieter does not discuss any possible crystal polymorphism of the disclosed compound.

Kirk-Othmer is cited for teaching that

> polymorphism is a condition in which a specific chemical compound may crystallize in different forms, that is, different space groups and with different physical and physico-chemical properties. An example is given of a simple compound, ammonium nitrate, with four form changes. In the paragraph which follows, it is stated that a specific **polymorph** may be absolutely essential for a particular crystalline product. By way of example, it is generally stated that one **polymorph** may have more desirable physico-chemical properties, i.e.[,] color, hardness, solubility or stability than another.
> ***2** Examiner's Answer, page 3.

The examiner notes that the instant claims are distinguishable over the prior art on the basis that it crystallized in three distinct crystalline forms, but states that "this does not render the compound in these crystalline forms patentable over the compound itself. The compound is neither new or novel, nor is its claimed use." Id. at 4. The rejection concludes that:

> It would have been obvious to one of ordinary skill in the art at the time of the invention that the three crystalline forms claimed by appellant[s] were intrinsic to the compound of the prior art, motivated by the fact that it is well known in the chemical arts that crystal polymorphism is a common and commonly recognized property of crystalline compounds.
> Id.

Appellants argue that the examiner has failed to set forth a prima facie case of obviousness. Specifically, appellants argue that, at best, the combination teaches that the claimed compound may have polymorphisms that may be separable, thus the rejection fails to provide a reasonable expectation of success in arriving at the claimed invention. See Appeal Brief, page 6. We agree.

The burden is on the examiner to make a prima facie case of obviousness, and the examiner may meet this burden by demonstrating that the prior art would lead the ordinary artisan to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988). The findings of fact underlying the obviousness rejection, as well as the conclusions of law, must be made in accordance with the Administrative Procedure Act, 5 U.S.C. § 706 (A), (E) (1994). See Zurko v. Dickinson, 527 U.S. 150, 158, 119 S.Ct. 1816, 1821, 50 USPQ2d 1930, 1934 (1999). Findings of fact underlying the obviousness rejection, upon review by the Court of Appeals for the Federal Circuit, must be supported by substantial evidence within the record. See In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). In addition, in order for meaningful appellate review to occur, the examiner must present a full and reasoned explanation of the rejection. See, e.g., In re Lee, 277 F.3d 1338, 1342, 61 USPQ2d 1430, 1432 (Fed. Cir. 2002).

The rejection of record does not meet the above criteria. Dieter, while teaching the compound that is the subject of the claims is known, does not teach or suggest that the compound has different crystalline structures. Thus, the rejection of record does not set forth any motivation to combine Dieter with Kirk-Othmer because, although Kirk-Othmer does teach that it is known that crystal polymorphism is known generally to exist, there is no teaching or suggestion in the references that the compound of the claimed invention is known to exhibit such polymorphism.

***3** Moreover, the record demonstrates that the compound as prepared by the prior art is a mixture of crystal **polymorphs,** whereas appellants have succeeded in isolating thee distinct **polymorphs,** i.e., Modifications A, B and C. See Declaration of Wilfried Thiel, Paper No. 9. Thus, the isolated crystal **polymorphs** as claimed in the instant application do not appear to be an inherent property of the claimed compound as disclosed by the prior art of record.

CONCLUSION

Because the rejection of record does not set forth a prima facie case of obviousness, it is reversed.

REVERSED

BOARD OF PATENT APPEALS AND INTERFERENCES

Sherman D. Winters

Administrative Patent Judge

Toni R. Scheiner

Administrative Patent Judge

Lora M. Green

Administrative Patent Judge

FN1. Note that the panel is interpreting this claim as requiring one of Modification A, Modification B or Modification C, but excluding mixtures of the disclosed modifications.

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END OF DOCUMENT

ATTACHMENT E

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(Cite as: 2003 WL 22282265 (Trademark Tr. & App. Bd.))

*1 THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)
EX PARTE RICHARD P. POLNIASZEK, XUEBAO WANG, JEFFREY S. DEPUE, CHENNAGIRI R. PANDIT, YADAGIRI PENDRI, AND EDUARDO J. MARTINEZ
Appeal No. 2001-1805
Application No. 09/141,402

NO DATE REFERENCE AVAILABLE FOR THIS DOCUMENT

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Before WINTERS, SCHEINER, and ADAMS

Administrative Patent Judges

ADAMS

Administrative Patent Judge

ON BRIEF

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claim 41, which is the only claim pending in the application and is reproduced below:

41. A high melt **polymorph** of the compound N-(3,4-dimethyl-5-isoxazolyl)-4'- (2-oxazolyl)[1,1'-biphenyl]-2-sulfonamide, which has a melting point of approximately 143.07 to 145.1° C.

The examiner relies on:

Murugesan 5,612,359 Mar. 18, 1997

GROUND OF REJECTION

Claim 41 stands rejected under 35 U.S.C. § 103 as obvious over Murugesan.

DISCUSSION

At the outset, we wish to make it clear that "reliance on per se rules of obviousness is legally incorrect" and must stop. In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). Accord, In re Brouwer, 77 F.3d 422, 425, 37 USPQ2d 1663, 1666 (Fed. Cir. 1996).

A per se approach would be in conflict with long standing precedent as to the relevance of the method of making a product to the obviousness of the product. Note In re Payne, ("[a]n invention is not 'possessed' absent some known or obvious way to make it.") citing In re Hoeksema, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968). In a similar manner, the court in In re O'Farrell, 853 F.2d 902, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988), in considering the Polisky reference relative to the rejected claims stated "Polisky contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful." (Emphasis added). See also, In re Lalu, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984)("[t]he prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compounds.")

***2** Since there are no per se rules of obviousness or nonobviousness, each case must be decided upon the facts in evidence in that case. See In re Cofer, 354 F.2d 664, 667, 148 USPQ 268, 271 (CCPA 1966) ("[n]ecessarily it is facts appearing in the record, rather than prior decisions in and of themselves, which must support the legal conclusion of obviousness under 35 U.S.C. § 103"); and Ex parte Goldgaber, 41 USPQ2d 1172, 1176 (Bd. Pat. App. & Int. 1995)("each case under 35 U.S.C. § 103 is decided on its own particular facts.").

We find the examiner's argument (Answer, page 4), "[t]he Court [in] In re Cofer expands upon rather than rejects what the Appellants term a 'purported [per se] rule"' legally flawed and in error. As set forth supra, our appellate reviewing court has made it clear that there are no per se rules of obviousness.

As a second error, we find that the examiner failed to provide any rationale or analysis to support her position in either the Answer or the Final Rejection. For emphasis we reproduce in full the examiner's statement of the rejection from page 3 of the Answer -- "Claim 41 is rejected under 35 U.S.C. [§] 103(a) as being unpatentable over ... Murugesan." In this regard, we suggest the examiner review the Manual of Patent Examining Practice (MPEP) § 706.02(j) for a model of how to explain a rejection under this section of the statute. Furthermore, we direct the examiner's attention to MPEP § 1208, "[a]n examiner's answer should not refer, either directly or indirectly, to more than one prior Office action." In this instance the Answer neither provides a reasoned explanation of the rejection, nor does it direct our attention to any prior Office action where a reasoned analysis of the facts is provided.

Contrary to the examiner's position (Answer page 5) [FN1], we find the N-(3,4-Dimethyl-5-isoxazolyl)-4'-(2-oxazolyl)[1,1'-biphenyl]-2-sulfonamide compound set forth in Example 1(D) of Murugesan to be the most relevant compound to appellants' claimed invention. However, as appellants point out (Brief, page 4) Murugesan "discloses an amorphous form of this compound, having a melting point of 90 to 98° C....." Stated differently, notwithstanding that the claimed compound has the same formula as Murugesan, the examiner has not established that Murugesan suggests appellants' specifically claimed **polymorph**. This is clearly demonstrated by the different melting points for the two compounds.

We note the examiner's analysis of the N-(3,4-Dimethyl-5-isoxazolyl)-4'-(5-oxazolyl)[1,1'-biphenyl]-2-Sulfonamide compound set forth in Murugensan's example 4, wherein she states (Answer, page 6) that a "difference in bonding location would result, as expected in any isomeric situation, in certain differences in physical properties. Here, one such difference is reflected in melting points that range from 189-191° C[] for the Murugesan compound compared to 143-145° C[] for the instantly claimed compound." However, the problem with this argument should be self evident (Answer, page 6), the "compound taught by Murugesan differs from the instantly claimed compound ... at the 5-oxazolyl position...." As appellants argue (Reply Brief, page 2), "[w]hile Example 4 of ... [Murugesan] indeed discloses a crystalline form of a compound having a melting point of 189-191° C, it fails to disclose or suggest the invention of claim 41 ... having a melting point of approximately 143-145° C." Stated another way, they are different compounds.

***3** The claimed invention is drawn to a specific polymorphic form of N-(3,4-

Dimethyl-5-isoxazolyl)-4'-(2-oxazolyl)[1,1'-biphenyl]-2-sulfonamide that has a melting point of approximately 143-145° C. The prior art relied upon by the examiner does not teach this specific **polymorph** as claimed by appellants. The examiner failed to demonstrate that the prior art even recognized that the claimed compound exists in different polymorphic forms, or that there is a known or obvious way to manufacture the specific polymorphic form claimed. Hoeksema. Stated differently, the examiner failed to demonstrate that Murugesan provides an enabling disclosure of the compound set forth in appellants' claim 41. In contrast the examiner has not rejected appellants' claims under 35 U.S.C. § 112, first paragraph, thus the examiner has found on this record that appellants' specification provides an enabling disclosure of how to make and use the claimed invention.

For the foregoing reasons we reverse the rejection of claim 41 under 35 U.S.C. § 103 over Murugesan.

REVERSED

BOARD OF PATENT APPEALS AND INTERFERENCES

Sherman D. Winters

Administrative Patent Judge

Toni R. Scheiner

Administrative Patent Judge

Donald E. Adams

Administrative Patent Judge

FN1. At page 5 of the Answer, the examiner finds that "[e]xample 4 of Murugesan is believed to be the most relevant and most critical to the issue of obviousness for the instant application.".

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END OF DOCUMENT